

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Covance Log Number (Test System)	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 0.0900 µg/mL-24/RT	8-9227	1	0.309	0.600	51.5	67.2	8.70	12.90	V3
	8-9227	2	0.383	0.600	63.8				
	8-9227	3	0.427	0.600	71.2				
	8-9227	4	0.411	0.600	68.5				
	8-9227	5	0.433	0.600	72.2				
	8-9227	6	0.456	0.600	76.0				
High QC 4.00 µg/mL-24/RT	8-9227	1	42.7	60.0	71.2	83.5	8.15	9.76	V3
	8-9227	2	47.5	60.0	79.2				
	8-9227	3	48.8	60.0	81.3				
	8-9227	4	52.3	60.0	87.2				
	8-9227	5	52.5	60.0	87.5				
	8-9227	6	56.9	60.0	94.8				

NA: Not applicable.

FIRST RUN
ROOM TEMP. STABILITY
(low QC messed, high
QC made it)

QC val exhalate, Stability(RT) (2)
1:57 PM 08/01/2001

DRAFT
Reviewed by: _____

Initial Run

PM3006635949

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Covance Log Number (Test System)	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 0.0900 µg/mL-24/RT	8-9227	1	0.465	0.600	77.5	81.3	3.64	4.48	V3
	8-9227	2	0.474	0.600	79.0				
	8-9227	3	0.469	0.600	78.2				
	8-9227	4	0.521	0.600	86.8				
	8-9227	5	0.498	0.600	83.0				
	8-9227	6	0.499	0.600	83.2				
High QC 4.00 µg/mL-24/RT	8-9227	1	35.8	60.0	59.7	66.8	4.41	6.60	V3
	8-9227	2	38.9	60.0	64.8				
	8-9227	3	39.8	60.0	66.3				
	8-9227	4	40.2	60.0	67.0				
	8-9227	5	42.6	60.0	71.0				
	8-9227	6	43.1	60.0	71.8				

NA: Not applicable.

SECOND RUN

Room Temp Stability

(high QC missed,
low QC made it)**DRAFT**

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Sample Identification	Covance Log Number (Test System)	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 0.0900 µg/mL-24/REF	8-9227	1	11.0	0.600	1830	2660	1395.3	52.5	V3
	8-9227	2	9.03	0.600	1510				
	8-9227	3	17.5	0.600	2920				
	8-9227	4	25.5	0.600	4250				
	8-9227	5	25.9	0.600	4320				
	8-9227	6	6.71	0.600	1120				
High QC 4.00 µg/mL-24/REF	8-9227	1	54.4	60.0	90.7	121	19.8	16.4	V3
	8-9227	2	84.6	60.0	141				
	8-9227	3	66.6	60.0	111				
	8-9227	4	71.5	60.0	119				
	8-9227	5	86.6	60.0	144				
	8-9227	6	73.1	60.0	122				

NA Not applicable.

First Run
Refrigerated stability

QC val exhalate, Stability, processed(REF) (2)
1:58 PM 08/01/2001

First Run

Analyst

Reviewed by

DRAFT

PM3006635951

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Covance Log Number (Test System)	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 0.0900 µg/mL-24/REF	8-9227	1	2.46	0.600	410	481	207.8	43.2	V3
	8-9227	2	1.36	0.600	227				
	8-9227	3	4.07	0.600	678				
	8-9227	4	2.53	0.600	422				
	8-9227	5	4.70	0.600	783				
	8-9227	6	2.21	0.600	368				
High QC 4.00 µg/mL-24/REF	8-9227	1	49.7	60.0	82.8	84.4	5.0	5.9	V3
	8-9227	2	47.8	60.0	79.7				
	8-9227	3	46.8	60.0	78.0				
	8-9227	4	53.4	60.0	89.0				
	8-9227	5	52.0	60.0	86.7				
	8-9227	6	54.0	60.0	90.0				

NA Not applicable.

SECOND RUN
 refrigerated stability
 Note the "marked
 improvement" in low
 QC recovery vs. the
 first run
 The high QC even
 makes it this time

DRAFT

Reviewed by: _____

QC val exhalate, Stability, processed(REF)
1:37 PM 08/01/2001

TOTAL P.05

PM3006635952